

110TH CONGRESS
1ST SESSION

H. R. 2295

To amend the Public Health Service Act to provide for the establishment
of an Amyotrophic Lateral Sclerosis Registry.

IN THE HOUSE OF REPRESENTATIVES

MAY 14, 2007

Mr. ENGEL (for himself, Mr. TERRY, Mr. WAXMAN, Mr. UPTON, Mr. MARKEY, Mr. WHITFIELD, Mr. TOWNS, Mr. SHIMKUS, Mr. RUSH, Mr. FOSSELLA, Mr. WYNN, Mrs. BONO, Mr. GENE GREEN of Texas, Mr. FERGUSON, Mrs. CAPPS, Mrs. MYRICK, Mr. DOYLE, Mr. ALLEN, Ms. SCHAKOWSKY, Ms. SOLIS, Mr. GONZALEZ, Mr. INSLEE, Ms. BALDWIN, Mr. ROSS, Mr. WEINER, Mr. MATHESON, Mr. BUTTERFIELD, Mr. BARROW, Ms. ROS-LEHTINEN, Mr. RANGEL, Mr. McCRERY, Mr. STARK, Mr. GOODE, Mr. KENNEDY, Mr. GERLACH, Mr. ROTHMAN, Mr. BURTON of Indiana, Mr. EMANUEL, Mr. SHAYS, Mr. HIGGINS, Ms. FALLIN, Mr. COHEN, Mr. BOUSTANY, Mr. PATRICK J. MURPHY of Pennsylvania, Mr. SMITH of New Jersey, Mr. McDERMOTT, Mr. BROWN of South Carolina, Ms. NORTON, Mrs. McMORRIS RODGERS, Mr. PRICE of North Carolina, Mr. McHUGH, Mr. ABERCROMBIE, Mr. EHLERS, Mr. McNULTY, Mr. GALLEGLY, Mr. McINTYRE, Mr. PEARCE, Mr. NADLER, Ms. CARSON, Mr. OLVER, Mr. TIERNEY, Mr. KANJORSKI, Mr. BISHOP of New York, Mr. MCGOVERN, Mr. CROWLEY, Mr. GRIJALVA, Mrs. LOWEY, Mr. SHERMAN, Ms. LORETTA SANCHEZ of California, Mr. MURTHA, Mr. ETHERIDGE, Mr. CAPUANO, Ms. KAPTUR, Mr. VAN HOLLEN, Mrs. MCCARTHY of New York, Ms. MCCOLLUM of Minnesota, Mr. BERMAN, Mr. SIRES, Ms. ROYBAL-ALLARD, Mr. CRAMER, Ms. HIRONO, Ms. BORDALLO, Mr. BOSWELL, and Mr. KIND) introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

To amend the Public Health Service Act to provide for
the establishment of an Amyotrophic Lateral Sclerosis
Registry.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “ALS Registry Act”.

5 **SEC. 2. FINDINGS.**

6 Congress makes the following findings:

7 (1) Amyotrophic lateral sclerosis (referred to in
8 this section as “ALS”) is a fatal, progressive
9 neurodegenerative disease that affects motor nerve
10 cells in the brain and the spinal cord.

11 (2) The average life expectancy for a person
12 with ALS is 2 to 5 years from the time of diagnosis.

13 (3) The cause of ALS is not well understood.

14 (4) There is only one drug currently approved
15 by the Food and Drug Administration for the treat-
16 ment of ALS, which has thus far shown only modest
17 effects, prolonging life by just a few months.

18 (5) There is no known cure for ALS.

19 (6) More than 5,000 individuals in the United
20 States are diagnosed with ALS annually and as
21 many as 30,000 individuals may be living with ALS
22 in the United States today.

23 (7) Studies have found relationships between
24 ALS and environmental and genetic factors, but
25 those relationships are not well understood.

1 (8) Scientists believe that there are significant
2 ties between ALS and other motor neuron diseases.

3 (9) Several ALS disease registries and data-
4 bases exist in the United States and throughout the
5 world, including the SOD1 database, the National
6 Institute of Neurological Disorders and Stroke re-
7 pository, and the Department of Veterans Affairs
8 ALS Registry.

9 (10) A single national system to collect and
10 store information on the prevalence and incidence of
11 ALS in the United States does not exist.

12 (11) In each of fiscal years 2006 and 2007,
13 Congress directed \$887,000 to the Centers for Dis-
14 ease Control and Prevention to begin a nationwide
15 ALS registry.

16 (12) The Centers for Disease Control and Pre-
17 vention and the Agency for Toxic Substances and
18 Disease Registry has established three pilot projects,
19 beginning in fiscal year 2006, to evaluate the science
20 to guide the creation of a national ALS registry.

21 (13) The establishment of a national registry
22 will help—

23 (A) to identify the incidence and preva-
24 lence of ALS in the United States;

1 (B) to collect data important to the study
2 of ALS;

3 (C) to promote a better understanding of
4 ALS;

5 (D) to collect information that is impor-
6 tant for research into the genetic and environ-
7 mental factors that cause ALS;

8 (E) to strengthen the ability of a clearing-
9 house—

10 (i) to collect and disseminate research
11 findings on environmental, genetic and
12 other causes of ALS and other motor neu-
13 ron disorders that can be confused with
14 ALS, misdiagnosed as ALS, and in some
15 cases progress to ALS;

16 (ii) make available information to pa-
17 tients about research studies for which
18 they may be eligible; and

19 (iii) maintain information about clin-
20 ical specialists and clinical trials on thera-
21 pies; and

22 (F) to enhance efforts to find treatments
23 and a cure for ALS.

1 **SEC. 3. AMENDMENT TO THE PUBLIC HEALTH SERVICE**
2 **ACT.**

3 Part P of title III of the Public Health Service Act
4 (42 U.S.C. 280g et seq.) is amended by adding at the end
5 the following:

6 **“SEC. 3990. AMYOTROPHIC LATERAL SCLEROSIS REG-**
7 **ISTRY.**

8 “(a) ESTABLISHMENT.—

9 “(1) IN GENERAL.—Not later than 1 year after
10 the receipt of the report described in subsection
11 (b)(2)(A), the Secretary, acting through the Director
12 of the Centers for Disease Control and Prevention
13 and in consultation with a national voluntary health
14 organization with experience serving the population
15 of individuals with amyotrophic lateral sclerosis (re-
16 ferred to in this section as ‘ALS’), shall—

17 “(A) develop a system to collect data on
18 ALS and other motor neuron disorders that can
19 be confused with ALS, misdiagnosed as ALS,
20 and in some cases progress to ALS, including
21 information with respect to the incidence and
22 prevalence of the disease in the United States;
23 and

24 “(B) establish a national registry for the
25 collection and storage of such data to include a
26 population-based registry of cases in the United

1 States of ALS and other motor neuron dis-
2 orders that can be confused with ALS,
3 misdiagnosed as ALS, and in some cases
4 progress to ALS.

5 “(2) PURPOSE.—It is the purpose of the reg-
6 istry established under paragraph (1)(B) to gather
7 available data concerning—

8 “(A) ALS, including the incidence and
9 prevalence of ALS in the United States;

10 “(B) the environmental and occupational
11 factors that may be associated with the disease;

12 “(C) the age, race or ethnicity, gender, and
13 family history of individuals who are diagnosed
14 with the disease;

15 “(D) other motor neuron disorders that
16 can be confused with ALS, misdiagnosed as
17 ALS, and in some cases progress to ALS; and

18 “(E) other matters as recommended by the
19 Advisory Committee established under sub-
20 section (b).

21 “(b) ADVISORY COMMITTEE.—

22 “(1) ESTABLISHMENT.—Not later than 90 days
23 after the date of the enactment of this section, the
24 Secretary, acting through the Director of the Cen-
25 ters for Disease Control and Prevention, shall estab-

lish a committee to be known as the Advisory Committee on the National ALS Registry (referred to in this section as the ‘Advisory Committee’). The Advisory Committee shall be composed of at least one member, to be appointed by the Secretary, acting through the Director of the Centers for Disease Control and Prevention, representing each of the following:

“(A) National voluntary health associations that focus solely on ALS and have demonstrated experience in ALS research, care, and patient services, as well as other voluntary associations focusing on neurodegenerative diseases that represent and advocate on behalf of patients with ALS and patients with other motor neuron disorders that can be confused with ALS, misdiagnosed as ALS, and in some cases progress to ALS.

“(B) The National Institutes of Health, to include, upon the recommendation of the Director of the National Institutes of Health, representatives from the National Institute of Neurological Disorders and Stroke and the National Institute of Environmental Health Sciences.

“(C) The Department of Veterans Affairs.

1 “(D) The Agency for Toxic Substances
2 and Disease Registry.

3 “(E) The Centers for Disease Control and
4 Prevention.

5 “(F) Patients with ALS or their family
6 members.

7 “(G) Clinicians with expertise on ALS and
8 related diseases.

9 “(H) Epidemiologists with experience in
10 data registries.

11 “(I) Geneticists or experts in genetics who
12 have experience with the genetics of ALS or
13 other neurological diseases.

14 “(J) Statisticians.

15 “(K) Ethicists.

16 “(L) Attorneys.

17 “(M) Other individuals with an interest in
18 developing and maintaining the National ALS
19 Registry.

20 “(2) DUTIES.—The Advisory Committee shall
21 review information and make recommendations to
22 the Secretary concerning—

23 “(A) the development and maintenance of
24 the National ALS Registry;

1 “(B) the type of information to be col-
2 lected and stored in the Registry;

3 “(C) the manner in which such data is to
4 be collected;

5 “(D) the use and availability of such data
6 including guidelines for such use; and

7 “(E) the collection of information about
8 diseases and disorders that primarily affect
9 motor neurons that are considered essential to
10 furthering the study and cure of ALS.

11 “(3) REPORT.—Not later than 1 years after the
12 date on which the Advisory Committee is estab-
13 lished, the Advisory Committee shall submit a report
14 concerning the review conducted under paragraph
15 (2) that contains the recommendations of the Advi-
16 sory Committee with respect to the results of such
17 review.

18 “(c) GRANTS.—Notwithstanding the recommenda-
19 tions of the Advisory Committee under subsection (b), the
20 Secretary, acting through the Director of the Centers for
21 Disease Control and Prevention, may award grants to, and
22 enter into contracts and cooperative agreements with, pub-
23 lic or private nonprofit entities for the collection, analysis,
24 and reporting of data on ALS and other motor neuron

1 disorders that can be confused with ALS, misdiagnosed
2 as ALS, and in some cases progress to ALS.

3 “(d) COORDINATION WITH STATE, LOCAL, AND FED-
4 ERAL REGISTRIES.—

5 “(1) IN GENERAL.—In establishing the Na-
6 tional ALS Registry under subsection (a), the Sec-
7 retary, acting through the Director of the Centers
8 for Disease Control and Prevention, shall—

9 “(A) identify, build upon, expand, and co-
10 ordinate among existing data and surveillance
11 systems, surveys, registries, and other Federal
12 public health and environmental infrastructure
13 wherever possible, including—

14 “(i) the 3 ALS registry pilot projects
15 initiated in fiscal year 2006 by the Centers
16 for Disease Control and Prevention and
17 the Agency for Toxic Substances and Dis-
18 ease Registry at the South Carolina Office
19 of Research & Statistics; the Mayo Clinic
20 in Rochester, Minnesota; and Emory Uni-
21 versity in Atlanta, Georgia;

22 “(ii) the Department of Veterans Af-
23 fairs ALS Registry;

24 “(iii) the DNA and Cell Line Reposi-
25 tory of the National Institute of Neuro-

logical Disorders and Stroke Human Genetics Resource Center;

“(iv) Agency for Toxic Substances and Disease Registry studies, including studies conducted in Illinois, Missouri, El Paso and San Antonio, Texas, and Massachusetts;

“(v) State-based ALS registries, including the Massachusetts ALS Registry;

“(vi) the National Vital Statistics System; and

“(vii) any other existing or relevant databases that collect or maintain information on those motor neuron diseases recommended by the Advisory Committee established in subsection (b); and

“(B) provide for research access to ALS data as recommended by the Advisory Committee established in subsection (b) to the extent permitted by applicable statutes and regulations and in a manner that protects personal privacy consistent with applicable privacy statutes and regulations.

“(2) COORDINATION WITH NIH AND DEPARTMENT OF VETERANS AFFAIRS.—Notwithstanding the

1 recommendations of the Advisory Committee estab-
2 lished in subsection (b), and consistent with applica-
3 ble privacy statutes and regulations, the Secretary
4 shall ensure that epidemiological and other types of
5 information obtained under subsection (a) is made
6 available to the National Institutes of Health and
7 the Department of Veterans Affairs.

8 “(e) DEFINITION.—For the purposes of this section,
9 the term ‘national voluntary health association’ means a
10 national non-profit organization with chapters or other af-
11 filiated organizations in States throughout the United
12 States.

13 “(f) AUTHORIZATION OF APPROPRIATIONS.—There
14 are authorized to be appropriated to carry out this section,
15 \$25,000,000 for fiscal year 2008, and such sums as may
16 be necessary for each of fiscal years 2009 through 2012.”.

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